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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,449	01/12/2004	Steve Dunfield	200208788-1	2134

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EXAMINER	
ROBINSON, JAMES MARSHALL	
ART UNIT	PAPER NUMBER
3772	

NOTIFICATION DATE	DELIVERY MODE
12/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

JERRY.SHORMA@HP.COM
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Office Action Summary	Application No.	Applicant(s)	
	10/756,449	DUNFIELD ET AL.	
	Examiner	Art Unit	
	James M. Robinson	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2007*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,9-15,46-48 and 53-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,9-15,46-48 and 53-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/9/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to amendments/arguments filed 08/09/2007. Currently claims 1, 3-7, 9-15, 46-48, and 53-57 are pending in the instant application. It is noted that applicant amended claims 1, 3-5, 9-13, 46, and 47; canceled claims 2, 16-23, and 49-52.

Response to Arguments

1. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3-7, 9-15, 46-48, and 53- 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Voges (US 5894841).

Voges discloses a method of dispensing one or more medicaments (col. 12, lines 9-13), comprising: providing a treatment plan having at least two rates of action for one or more medicaments (col. 11 line 66- col. 12 line 2); selecting a different droplet size characteristic corresponding to each of the at least two rates of action; and ejecting medicament droplets having each different droplet size (col. 8, lines 45-51) characteristic into a respiratory system of a subject (col. 5, lines 20-25) according to the

treatment plan, thereby allowing the one or more medicaments to act at two or more rates; wherein selecting the different droplet size includes selecting a droplet size according to a predicted change in the droplet size produced during flight (col. 7 lines 4-15) of the medicament droplets after ejection; wherein ejecting medicament droplets includes ejecting medicament droplets having each different droplet size (col. 8, lines 45-51) characteristic from a distinct set of orifices (col. 4, lines 53-58) of the same medicament ejection apparatus; wherein selecting the different droplet size characteristic includes selecting a different medicament composition (col. 7, lines 15-29) for each rate of action, and wherein ejecting medicament droplets includes ejecting medicament droplets having each different medicament composition; wherein selecting the different medicament composition includes selecting the same bioactive agent (col. 7, lines 4-14) for each different medicament composition; wherein selecting the different droplet size includes selecting a size of medicament droplet according to a deposition site (col. 8, lines 22-27) for the size of medicament droplet in the respiratory system, the deposition site defining an absorption rate that corresponds to one of the at least two rates of action, wherein ejecting medicament droplets includes forming medicament droplets of each droplet size adjacent orifices (col. 8, lines 45-51) of a corresponding size; wherein ejecting medicament droplets includes ejecting medicament droplets of different sizes at nonoverlapping times (col. 7, lines 36-41); wherein ejecting medicament droplets includes ejecting medicament droplets of each different droplet size within the same dose (col. 8, lines 45-51); selecting a composition for each different droplet size (col. 11 line 66- col. 12 line 2); wherein the composition is

selected from compositions having different amounts of the same bioactive agent; (col. 7, lines 15-29); wherein ejecting medicament droplets includes ejecting the same medicament composition for each different droplet size characteristic (col. 11 line 66-col. 12 line 2); wherein providing the treatment plan includes providing a treatment plan to treat addiction to nicotine, and wherein at least one of the medicaments includes nicotine (col. 6, lines 17-19) or a nicotine analog; wherein ejecting medicament droplets includes ejecting medicament droplets targeted for deposition on respective upper and lower mucosal regions of the respiratory system; wherein ejecting medicament droplets includes ejecting medicament droplets of different droplet sizes targeted for deposition on an oral or nasal mucosal region and a pulmonary (col. 1, lines 61-66) mucosal region; wherein selecting the different droplet size includes selecting a medicament composition with the same drug for each different droplet size. wherein selecting the different droplet size includes selecting a medicament composition with the same drug for each different droplet size (col. 8, lines 45-51); wherein ejecting medicament droplets includes ejecting medicament droplets having a drug and a flavoring agent (col. 8, lines 39-44).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voges (US 5894841) in view of Childers et al. (US 6886557). Voges substantially discloses the invention as claimed; see rejection to claim 1 above. However, Voges is silent to ejecting placebo droplets without the drug and sized for deposition on an oral mucosal region instead of ejecting medicament droplets having the drug.

Childers et al. discloses an method for delivering multiple inhalable materials in programmably varying amounts over time (col. 1, lines 50-51) including first and second microfluidic generators or emitters (col. 1, lines 51-55) which utilizes ejection of materials which are considered pharmacologically inactive; wherein placebos are administered instead of drug medicament droplets having a drug in order to provide user with a measure of satiation or satisfaction. (col. 5 line 64- col. 6 line 5).

5. It would have been obvious to modify the method of Voges to include ejecting placebo droplets without the drug and sized for deposition on an oral mucosal region instead of ejecting medicament droplets having the drug as taught by Childers in order to utilize provide psychological satisfaction to a user while limiting the amount of drug delivered in order to wean a user off of cigarettes.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Robinson whose telephone number is (571) 270-3867. The examiner can normally be reached on Mon-Fri 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James M. Robinson/

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772